

Technological and Administrative Factors Implementing a Virtual Human Biospecimen Repository

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Abstract

The value of human biospecimens available for research dramatically increases when linked with their accumulated clinical and molecular (genomic, proteomic, subcellular modeling) data. Further, informatics tools make it possible for researchers (both intra- and inter-institutionally) to locate tissue needed for research faster and more reliably. We are developing a virtual human biospecimen repository to both inventory and link all human biospecimens with clinical and genomics data to optimize their value for research, while satisfying all privacy and human subjects protections regulations.

Administration and Process Control:

Critical to the success of any research biospecimen repository are the institutional policies and processes put into place to effectively manage its operation. Our institution created a Human Tissue Oversight Committee (HTOC) to develop and administer the necessary policy and processes. The HTOC is composed of faculty with pathology, oncology, informatics, research, clinical, regulatory, and administrative backgrounds. Working closely with the institution's Human Research Review Committee (HRRC) the HTOC identified four types of tissue that would be collected from patients and the corresponding four levels of patient consent for use with all biospecimens stored in the repository:

Type A. Excess tissue alternatively prepared for possible future diagnostic purposes. (No IRB oversight or consent status as tissue prepared for diagnostic studies only.)

Type B. Excess tissue alternatively prepared for a known HRRC-approved active research project with HRRC-approved consent status.

Type C. Excess tissue alternatively prepared for unknown future research project with Tissue Repository consent of patient.

Type D. Excess tissue alternatively prepared for unknown future research project with waiver of informed consent, waiver of HIPAA authorization, Tissue Repository as honest broker for identifiers and dispensed as de-identified samples.

The HTOC has a policy and process in place to assure all biospecimen based research has appropriate HRRC approval. Further, the HTOC also reviews all requests for repository biospecimens for scientific merit to insure the most appropriate use of all biospecimens, especially when they may be rare. (Our poster diagrams this process in detail.)

Biospecimen Processing:

Although our virtual repository is capable of tracking biospecimens physically stored in any location in our institution, currently we have a central lab core area that prospectively collects and stores the majority of the biospecimens entered into our repository for future research (not for a current cooperative or local protocol.)

Informatics Support:

Also critical to the success of the virtual repository is strong informatics support. The HTOC's technical subcommittee identified the following functionalities as key components of the informatics tool needed:

- Support for a 4-level patient consent system.
- Strong audit trail capabilities.
- Highly configurable user privileges to support user types that allow both effective administration and highly restricted access to support de-identified-only queries.
- Data dictionary support tools, including specific support for SNOMED and LOINC.
- HL-7 Interface/external database linking capability.
- Strong database query functionality.
- Clinical/genomics data storage capability that is highly configurable.

Work in Progress to Date:

Currently there are 1300 samples stored in the repository and we are acquiring approximately 15 per month on average for the last half of 2004. We are in the process of converting from a small Microsoft Access database to an Oracle-based system designed with the key components listed above that will greatly enhance our query and administrative capabilities.